

**REMARKS**

***Status of the Claims***

The present Office Action addresses and rejects claims 1-5, 7-21, 23, 25, and 27-35, however claims 13, 14, 19, 20, 24, and 32 are withdrawn. Applicant respectfully requests reconsideration in view of the remarks herein.

***Rejections Pursuant to 35 U.S.C. § 103***

**Mazel in view of Shih**

Claims 1-5, 7-9, 12, 15, 18, 21, 23, and 25-31 are rejected pursuant to 35 U.S.C. §103(a) as being made obvious by U.S. Patent Publication No. 2005/0171537 of Mazel et al. (“Mazel”) in view of U.S. Patent No. 6,136,002 of Shih et al. (“Shih”).

**Claim 1**

In relevant part, independent claim 1 recites a fastening element that extends through a bore in a spinal anchoring element, and a set screw having a head that is received within the tapered bore in the closure mechanism, and a threaded shaft adapted to threadably engage threads in the bore in the spinal anchoring element to mate the closure mechanism to the spinal anchoring element.

The Examiner argues that Mazel discloses the device of claim 1, but admits that Mazel does not disclose a tapered bore in the closure mechanism.<sup>1</sup> The Examiner thus relies on Shih to remedy the deficiencies of Mazel. Applicant respectfully disagrees.

Mazel and Shih are deficient, taken alone or combined, because there is simply no teaching in either reference to insert a set screw through the same bore as a fastening element and to use the set screw to mate the closure mechanism to the spinal anchoring element.

Regardless of whether or not it would have been obvious to modify Mazel in view of Shih, the combination of Mazel and Shih simply does not teach the claimed invention. With reference to

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<sup>1</sup> Applicants further note that Mazel’s set screw 28 does not have a head, as required by claim 1. The set screw is clearly headless, and is only in the form of a threaded shaft.

Figures 1 and 2 of Mazel, reproduced below, the Examiner asserts that threaded plug 28 of Mazel forms the claimed set screw, upper element 7 and nut 14<sup>2</sup> form the claimed closure mechanism, and lower element 6 forms the claimed spinal anchoring element.

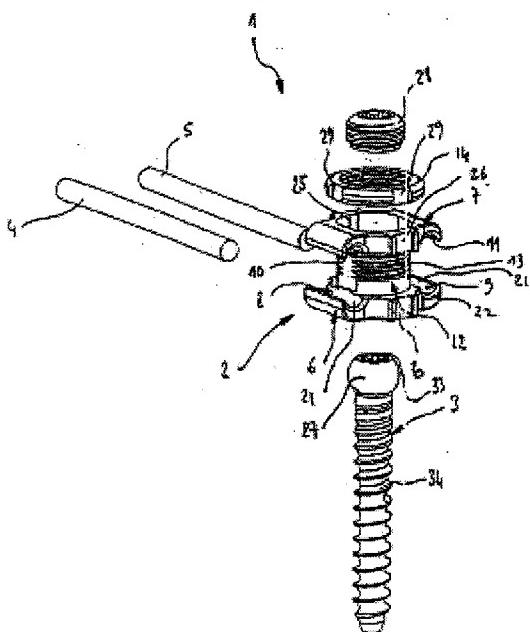


Figure 1

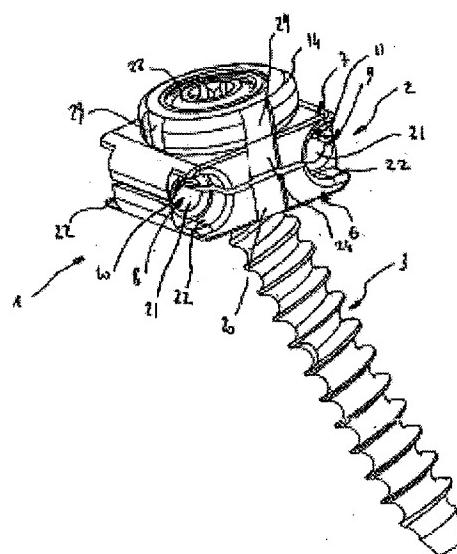


Figure 2

If Mazel's closure mechanism (7, 14) is modified to have a tapered bore, as taught by Shih, the combination would not result in the claimed because Mazel would still lack a set screw that "mate[s] the closure mechanism to the spinal anchoring element," as specifically required by claim 1. Mazel's set screw (28) does not mate the closure mechanism (upper element 7 and nut 14) to the spinal anchoring element (lower element 6) as required by claim 1. Mazel specifically states that "the second element 7 is immobilized on the first one 6 with the aid of the nut 14 which cooperates with the external thread 13 of the sleeve 12." Mazel, para. [0052]. It is thus the *nut 14* – not the plug 28 - that mates the lower and upper elements 6, 7 together. The plug 28 is applied *after* the upper element 7 and the nut 14 have been fixedly secured to the lower element 6, and the plug simply fixes the screw 3 in a desired polyaxial position relative to the lower and upper elements 6,

<sup>2</sup> The Examiner states on page 2 of the Office Action that the "closure mechanism" in Mazel includes elements numbered 7 and 29. However, element 29 merely refers to notches on the nut 14. Hence, Applicant presumes that the Examiner intended for the closure mechanism in Mazel to include the upper element 7 and the *nut 14*. Applicant respectfully requests clarification if the Examiner intended otherwise.

7. *See id.* at para. [0054]. Thus, even if Mazel is modified in view of Shih to have a tapered bore, the combination fails to disclose a set screw that mates the closure mechanism (7, 14) to the spinal anchoring element (2), and therefore claim 1 distinguishes over Mazel and Shih.

Applicants further note that, while Shih does disclose a set screw that mates a closure mechanism to a spinal anchoring element, in Shih the set screw S is not inserted through the same bore that receives the fastening element. Claim 1 requires that a fastening element extend through a bore in a spinal anchoring element, and that the set screw threadably engages threads in the bore in the spinal anchoring element. Thus, both the fastening element and the set screw must extend into the same bore. Shih's locking nut (S) extends through a bore in the cover plate (14) and threads into a hole (H) in the vertebral plate (12), and the bolts (B) extend through separate bores in the vertebral plate (12). Thus, while Shih discloses a set screw that mates a closure mechanism to a spinal anchoring element, the only possible way to modify Mazel in view of Shih to use the set screw (28) to mate the closure mechanism (7, 14) to the spinal anchoring element (2), as required by claim 1, would be to reconfigure Mazel's device to have separate bores for the set screw and the fastening element, as taught by Shih. Such a configuration would not result in the claimed invention because the set screw and the fastening element would no longer be in the same bore. There is simply no teaching in either reference to insert a set screw through the same bore as a fastening element and to use the set screw to mate the closure mechanism to the spinal anchoring element.

Accordingly, claim 1 represents allowable subject matter at least because the combination of Mazel and Shih does not teach the claimed invention.

### **Claim 21**

In relevant part, independent claim 21 recites at least one of the spinal anchoring devices being adapted to receive a fastening element for mating the spinal anchoring device to bone and a locking mechanism *axially aligned* with the fastening element to lock the first and second spinal fixation elements to the spinal anchoring device. Claim 21 also requires that at least one of the plurality of spinal anchoring devices includes a spinal anchoring element and a closure mechanism adapted to removably mate to the spinal anchoring element to lock the first and second flexible spinal fixation elements therein, the locking mechanism being adapted to threadably mate with a

bore formed in the spinal anchoring element to mate the closure mechanism to the spinal anchoring element.

The Examiner fails to specifically address any of the language in claim 21, but presumably the Examiner is applying Mazel to claim 21 similar to its application to claim 1, likening the threaded plug 28 of Mazel to a locking mechanism, the upper element 7 and nut 14 to a closure mechanism, and the lower element 6 to a spinal anchoring element.

For similar reasons discussed above with respect to claim 1, the combination of Mazel and Shih does not teach the claimed invention. If Mazel is modified in view of Shih to include a tapered bore, the combination still fails to disclose a locking mechanism that mates the closure mechanism (7, 14) to the spinal anchoring element (2). As discussed above, Mazel's set screw does not mate the closure mechanism to the spinal anchoring element, but rather it merely locks the head of the fastening element in a fixed axial position relative to the spinal anchoring element (2).

While Shih discloses a set screw that mates a closure mechanism to a spinal anchoring element, the only possible way to modify Mazel in view of Shih to use the set screw (28) to mate the closure mechanism (7, 14) to the spinal anchoring element (2), as required by claim 21, would be to reconfigure Mazel's device to have separate bores for the locking mechanism and the fastening element, as taught by Shih. Such a configuration would not result in the claimed invention because the locking mechanism and the fastening element would no longer be axially aligned, as required by claim 21. There is simply no teaching in either reference to insert a locking mechanism screw through the same bore as a fastening element (so that they are axially aligned) and to use the locking mechanism to mate the closure mechanism to the spinal anchoring element.

Accordingly, claim 21 represents allowable subject matter at least because the combination of Mazel and Shih does not teach the claimed invention.

In sum, claims 1 and 21, as well as claims 2-5, 7-9, 12, 15, 18, 23, 25-31 which depend therefrom, distinguish over Mazel and Shih, alone or in combination, and represent allowable subject matter.

**Mazel in view of Paul**

Claims 16, 17, 34, and 35 are rejected pursuant to 35 U.S.C. §103(a) as being made obvious by Mazel in view of U.S. Patent Publication No. 2004/0236327 of Paul et al. (“Paul”). Applicant respectfully disagrees.

At the outset, Applicant notes that this rejection appears to be incomplete. Applicant presumes that the Examiner intended to reject claims 16, 17, 34, and 35 as being obvious over Mazel, Paul, *and Shih* because claims 16, 17, 34, and 35 ultimately depend from either independent claim 1 or independent claim 21, which are rejected over Mazel *and Shih*. If the Examiner intended otherwise and issues an office action in response to this paper rejecting claims 16, 17, 34, and 35, Applicant respectfully requests a non-final Office Action in order to develop a clear issue between the Examiner and Applicant. MPEP §706.07.

At least for the reasons explained above, Mazel and Shih do not teach the invention recited in independent claims 1 and 21 from which claims 16, 17, 34, and 35 depend. Paul is only relied on for dependent claim features, namely the spinal fixation elements including flexible fixation elements and the spinal fixation elements being formed from a bioabsorbable material, and does not remedy the deficiencies of Mazel and Shih. Accordingly, claims 16, 17, 34, and 35 are allowable at least because they depend from an allowable base claim.

***Conclusion***

Accordingly, all claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

No extension of time is believed to be due with this filing. In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

All fees due are believed to be paid. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 101896-251.

Dated: November 3, 2009

Respectfully submitted,

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